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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,586	04/24/2000	MAURIZIO VALLERI	515-4183	6516
7590	07/22/2004		EXAMINER	
JAMES V COSTIGAN HEDMAN GIBSON & COSTIGAN 1185 AVENUE OF THE AMERICAS SUITE 2003 NEW YORK, NY 10036-2601			KISHORE, GOLLAMUDI S	
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/463,586

Filing Date: April 24, 2000

Appellant(s): VALLERI, MAURIZIO

James V. Costigan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9-5-2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Claims 1-8 and 13-18 have been grouped together.

Claim 19 is grouped separately.

(8) ClaimsAppealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,576,021	ANDOH et al.	11-96
4,493,822	TOVEY	1-85

Remington's Pharmaceutical Sciences, Eighteenth Edition, Mack Publishing Company, Easton, Pennsylvania, 1990, pp. 1635-1636.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC. 103

Claims 1-8, and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR .2 724 844 to Meignant et al. in view of US Patent 5,576,021 to Andob et al. OR US Patent 4,493,822 to Tovey OR Remington's Pharmaceutical Sciences.

Meignant et al. disclose a therapeutic composition of vitamins and calcium, in the form of tablets, comprising elemental calcium and at least one vitamin D. Meignant et al. further teach that the calcium is present in salt form, and can be calcium carbonate, calcium pidolate,

calcium chloride, calcium glycerophosphate, calcium lactate, calcium citrate, calcium gluconate or calcium phosphate (p 1, claim 2). Meignant et al. also teach that the vitamin D can be in the form of vitamin D2 or D3 (page 11, claim 3). Additionally, Meignant et al. teach the inclusion of well-known excipients, such as binders, lubricants, diluents, and flavor agents (p 2, 1 20-35). Meignant et al. also teach that the formulation can be in tablet or sachet form (p 13, claim 13). Lastly, Meignant et al. teach a process for making the formulation, including granulating the components and mixing them

together, prior to making the final dosage form (p 13, claim 14). Meignant et al. teach 1250 mg of calcium carbonate (which corresponds to 500 mg of elemental calcium) and 4 mg of vitamin 173 (Which corresponds to 400 IU). This fulfills the ratio requirement of applicant's instant claim 1. Instant claim states that the calcium salt must be present in a ratio of 1-2 g of elemental calcium for each 500-1000 IU of vitamin D. Meignant c/ al. teach the identical ratio, as the amounts are simply divided by 2. Therefore, Meignant et al. teach the weight requirements of applicant's instant claims. Meignant et al. do not teach each of the binders claimed by applicant. However, Meignant et al. do teach the presence of a very well known pharmaceutical binder, polyvinyl pyrrolidone.

Andoh et al. teach an improved oral dosage form. This reference is relied upon for the teachings of equivalency between polyvinyl pyrrolidone and polyethylene glycol as tablet binders. See column 9, claim 4, and column 10, claim 12.

Additionally, Tovey teach pharmaceutical dosage units. Tovey is also relied upon for the teaching of equivalency between polyvinyl pyrrolidone and polyethylene glycol as tablet binders. See column 5, lines 1-13.

Additionally, Remington's Pharmaceutical Sciences discloses a list of binders to be used in pharmaceutical formulations. Remington's teaches polyvinyl pyrrolidone, polyethylene glycol, and waxes. It is the position of the examiner that the disclosure to waxes teaches the equivalency between PVP, PEG, and liquid paraffin. See page 1635, column 2, last 2 paragraphs.

It is the position of the examiner that absent comparative scientific data teaching otherwise, one of ordinary skill in the art would have been motivated to use any well

known tablet binder in the composition of Meignant et al., with the same expected result, especially

because Meignant et al. teach that their invention is useful for the same purpose of combating osteoporosis as applicant's composition. This is reiterated with the teachings of equivalency provided by Andoh c/ al., Tovey, and Remington's. There has been no comparative evidence provided to convince the examiner that the use of one binder versus another would provide patentable distinction between the instant application and the cited prior art.

For the above reasons, this invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that Meignant does not teach the amount of calcium and Vitamin D claimed by Applicant, because Applicant's claims require a minimum amount of 500 I.U. of Vitamin D with a minimum amount of 1 g of calcium. The examiner directs Applicant's attention to page 7 –8 of the French document, or page 13 of the attached English translation. This portion of the cited reference teaches that the doses which can be generally used with respect to their invention include calcium in an elementary form, from about 500 mg to about 1500 mg, and vitamin D, or a mixture of vitamin Ds, from about 2 mg to about 12 mg. Therefore, the reference does teach Applicant's claimed minimum amount of vitamin D, as well as Applicant's claimed ratio, as discussed in the above rejection. Applicant further argues that Meignant refers

to pharmaceutical composition which must be prepared in a "humid environment."

Referring to the attached English translation again, the examiner finds no teaching in claim 4 of the reference, which requires a humid environment. Since there is no indication of the presence of water in Meignant, applicant's arguments based on the amendment to claim 1 reciting 'consisting essentially of' and thus, excluding possible presence of water in Meignant are not persuasive. Applicant also asserts that the preferred calcium salt is calcium phosphate and its analogs.

Applicant argues that Meignant does not teach the necessary limitations to have success with calcium phosphate. This argument is unpersuasive for two reasons. First, calcium phosphate is not a limitation in the independent claim, and therefore this argument is not commensurate in scope with all of the instant claims. Second, Meignant specifically teaches the use of calcium phosphate. Therefore, the reference is clearly suggestive of using this particular form of calcium. Lastly, Applicant argues that the PEG cited by the examiner is not the same PEG cited by Applicant. It remains the position of the examiner that absent evidence to the contrary, based on the teachings above; PEG is a well-known excipient. The examiner pointed out in the final rejection that the burden is shifted to applicant to show unexpected results found when using a particular form of PEG and any results should be in declaration form, with statistical analysis, and should rely solely on the particular form of PEG. This has not been done by applicant.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

S Kishore
Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK
July 19, 2004

Conferees

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER
AU 1646

JAMES V COSTIGAN
HEDMAN GIBSON & COSTIGAN
1185 AVENUE OF THE AMERICAS
SUITE 2003
NEW YORK, NY 10036-2601